



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 4, 2014

Advanced Vascular Dynamics
Mr. Matthew Semler
President
4252 SE International Way, Suite F
Milwaukie, Oregon 97222

Re: K142122
Trade/Device Name: Radar Vascular Compression Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: October 1, 2014
Received: October 2, 2014

Dear Mr. Semler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142122

Device Name: RadAR™ Vascular Compression Assist Devices

Indications for Use:

The RadAR™ Vascular Compression Devices are indicated for use by medical professionals to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's arm or leg, including: radial, brachial, dorsalis pedis or tibial blood vessels, arterial or venous line or sheath removal, hemodialysis, and in patients on anticoagulation therapy.

Prescription Use X

(Part 21 CFR 801 Subpart D)

Over-The-Counter Use

(21 CFR 801 Subpart C)

AND/OR

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Submitter's name: Advanced Vascular Dynamics
4252 SE International Way, Ste. F
Milwaukie, OR 97222

Contact name and address: Matthew Semler, President
4252 SE International Way, Ste. F
Milwaukie, OR 97222
(503-223-2333 ext. 382)

Date summary prepared: 14 November 2014

Device name:

Proprietary name: RadAR™ Vascular Compression Devices
Common or usual name: Vascular compression device
Classification name: Vascular clamp (870.4450), Vascular clamp (74 DXC)

Legally marketed device for substantial equivalence comparison:

The predicate devices for this submission are the RadAR™ Vascular Compression Devices submitted by Advanced Vascular Dynamics and cleared for marketing under 510(k) K092503, and the HemoBand®, manufactured by Innovations for Access, Inc. (K081740).

Description of the device:

The RadAR™ Vascular Compression Devices consist of a strap with a housing with controls for device securement and adjustment, and a compression pad. The product is designed to reduce blood flow in the subject blood vessel compressed by the pad, while allowing blood flow in other vessels in the arm or the leg to promote hemostasis at the vascular puncture site. The user can delicately control the compression applied by the device without unfastening it. This allows gradual release of compression as hemostasis occurs and, at the user's discretion, permits blood flow into the compressed blood vessel during puncture site hemostasis. This device is not life supporting or life sustaining. The product is provided individually packaged. It is a sterile, single use device.

Intended use of the device:

The RadAR™ Vascular Compression Devices are indicated for use by medical professionals to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's arm or leg, including: radial, brachial, dorsalis pedis or tibial blood vessels, arterial or venous line or sheath removal, hemodialysis, and in patients on anticoagulation therapy.

Technological characteristics:

The device features of the RadAR™ Vascular Compression Devices and the HemoBand® Device are similar. They are adjustable straps that are applied around an arm or a leg, to apply pressure to a restricted area. There are some design variations, but the means of applying external compression for the purpose of reducing blood flow in the subject blood vessel remains substantially equivalent, in that a device is pressed against a portion of the limb.

Testing conducted:

Since this submission applies to the RadAR™ Vascular Compression Devices to revise the indications for use, no additional testing has been deemed to be required. As its own predicate device, the device, production, and sterilization testing reported in K092503, apply. Although no new testing was performed, testing on the predicate device has been leveraged to demonstrate that the submitted device is appropriate for the new indications for use. No further testing has been deemed necessary.

Performance Testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).

Conclusion:

Previous testing on the submitted RadAR™ Vascular Compression Device has demonstrated that this device is as safe and as effective as the predicate devices.